DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/14/2010 has been entered.

Notice of Amendment

2. In response to the amendment filed on 06/14/2010, amended claim(s) 1, 27, and 65 is/are acknowledged. The previous rejection(s) of the claims is/are *withdrawn*. The following is/are set forth:

Information Disclosure Statement

3. The information disclosure statement(s) (IDS) submitted on 03/03/2010 and 09/03/2010 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

4. The Examiner notes however that several foreign patent documents were not considered, as indicated on the attached IDS, because English translations of at least the abstract did not appear present with the submissions.

5. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

EXAMINER'S AMENDMENT

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Paul Davis on 09/02/2010.

The application has been amended as follows:

Claim 1 should read as follows:

1. A body fluid sampling system for use on a tissue site, the system comprising:

a disposable;

a penetrating member driver;

a plurality of penetrating members arranged in a radial configuration in the disposable, wherein sharpened distal tips of the penetrating members point radially

outward**, and wherein each of the plurality of penetrating members has a packing density of about 0.1 cm^3**;

wherein an active one of said penetrating members **[may be]is** operatively coupled to said penetrating member driver, said penetrating member driver moving said active one **of said penetrating members** along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

a processor coupled to the penetrating member driv**[ing]er and** configured to provide instructions to the penetrating member driver for a fast-into of **said active one** penetrating members into **[a]the** tissue site and slow-out velocity out of the tissue site; and

a plurality of analyte detecting members positioned in the disposable, wherein at least one of said analyte detecting members is positioned to receive **less than about 0.1 µL of body** fluid from a wound created by said active one of said penetrating members, **and** wherein said **plurality of analyte** detecting members are not pierced by the active one of the penetrating members.

Claim 13 should read as follows:

13. A system as in claim 1**,** further comprising a penetrating member sensor positioned to monitor the active one of said penetrating members coupled to said penetrating member driver, the penetrating member sensor configured to provide

information relative to a depth of penetration of **[a]the active one of said** penetrating member**s** through a skin surface **of the tissue site**.

Claim 16 should read as follows:

16. The system of claim 13, wherein the depth of penetration is no more than about 1000 microns beyond a stratum corneum thickness of **[a]the** skin surface.

Claim 17 should read as follows:

17. The system of claim 13, wherein the depth of penetration is no more than about 500 microns beyond a stratum corneum thickness of **[a]the** skin surface.

Claim 24 should read as follows:

24. The system of claim 1, wherein the processor is utilized to monitor position and speed of the active one of said penetrating members as the **active one of said** penetrating member moves in a first direction.

Claim 65 should read as follows:

65. A body fluid sampling system for use on a tissue site, the system comprising:

a disposable;

a penetrating member driver;

a plurality of penetrating members arranged in a radial configuration in the disposable**,** wherein sharpened distal tips of the **plurality of** penetrating members point

radially outward**, and wherein each of the plurality of penetrating members has an elongate portion and a packing density of about 0.1 cm^3**;

wherein an active one of said penetrating members **[may be]is** operatively coupled to said penetrating member driver, said penetrating member driver moving said active one **of said penetrating members** along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site;

a processor coupled **[feedback and]**to the penetrating member driv**[ing]er and** configured to provide **feedback and** instructions to the penetrating member driver for a fast-into **velocity** of **said active one of said** penetrating members into **[a]the** tissue site, a rest time of **[a]the sharpened distal tip** of **[a] said active one of said** penetrating member**s** in the tissue site**,** and a slow-out velocity **of said active one of said penetrating members** out of the tissue site;

a plurality of analyte detecting members positioned in the disposable, wherein at least one of said analyte detecting members is positioned to receive **less than about 0.1 µL of body** fluid from a wound created by said active one of said penetrating members, **and** wherein said **plurality of analyte** detecting members are not pierced by the active one of the penetrating members; and

a coupler on said penetrating member driver configured to engage at least a portion of said elongate portion of **[the]said active one of said** penetrating member**s** and **to** drive said **active one of said penetrating** member**s** along **[a]the** path into the tissue site and **to** withdraw[n] **it** from the tissue site.

Allowable Subject Matter

7. Claims 1, 13-17, 21, 24, 27, 57, and 65 are allowed.

8. The following is an examiner's statement of reasons for allowance: the prior art does not disclose, teach, and/or fairly suggest a body fluid sampling system comprising *inter alia*: a cartridge housing a plurality of lancets having an occupied volume of about 0.1 cm^3 and a plurality of analyte sensors receiving less than about 0.1 µL of body fluid, wherein an active one of the lancets is coupled to a driver that drives the active lancet into the tissue, stops it in the tissue, and retracts it from the tissue, wherein a processor is coupled to the driver and instructs it to drive the active lancet with a fast velocity into the tissue and with a slow velocity out of the tissue.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736